UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,554	07/23/2001	Edmund Scholl	24669	6387

20529 7590 02/04/2005

NATH & ASSOCIATES
1030 15th STREET, NW
6TH FLOOR
WASHINGTON, DC 20005

EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,554	SCHOLL, EDMUND	
	Examiner	Art Unit	
	Sharon L Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The examiner acknowledges receipt of the Amendment, the Remarks and the extension of time filed on 8/5/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-30 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wahlig '013.

Wahlig teaches a composition consisting of a drug delivery system comprising collagen, which is resorbable in the body. Wahlig teaches collagen in lyophilized form, with a delayed release of active materials. See column 3, lines 11-30 and column 2, lines 36-67. Wahlig teaches collagen having spheroidal shaped bodies of various dimensions, for example, spheroids with a diameter of 0.5-10mm, and granulates with a diameter of 0.1-5 mm. Wahlig also teaches that the composition can also be formed into a powder. See column 2, lines 63-68, bridging column 3, lines 1-10. Wahlig teaches the active materials consists of antibiotics such as two or more aminoglycoside antibiotics which include gentamycin and clindamycin. See column 5, lines 8-40. In addition, Wahlig teaches calcium phosphate and tricalcium phosphate. See column 6, lines 1-9. The reference clearly teaches resorbable collagen in lyophilized form with a delayed release of active materials.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-28,30-55 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chu (U.S. Patent No. 5,219,576).

Chu teaches collagen wound healing matrices and a method for making biodegradable collagen implants, formed of collagen fibrils that are not chemically cross-linked, having a bulk density of 0.01 to 0.3 g/cm^3 and having at least about 80% of pores which normally has a pore size of 35 to 250 microns in diameter. Chu further discloses that the wound healing matrix serves as an effective sustained delivery system for bioactive agent. See abstract and column 6, line 68, bridging column 7, lines 1-10.

Chu discloses a method for making collagen implants by providing an acidic aqueous solution of collagen, precipitating the collagen from the solution, and forming a homogeneous dispersion of the precipitated collagen fibrils, casting the dispersion in a mold to a desired thickness, flash-freezing the cast dispersion at a temperature belose about –20 degrees C; and lyophilizing the frozen cast dispersion to form a collagen implant. Bioactive additives can be added to the homogeneous dispersion before or after the pH of the solution has been adjusted. See column 2, lines 18-36. Chu teaches that glycosaminoglycans, bioactive and/or non-bioactive agents are added to

the collagen dispersion prior to flash-freezing and lyophilization. See column 5, lines 15-18. Adding heparin to the dispersion has been found to affect the pore size of the implant. See column 6, lines 52-58. Chu also teaches that the fibrous implants are about 2 to about 8 mm thick and that the implants may easily be cut to shape in order to fill the wound closely. See column 7, lines 15-30.

The reference meets the claims of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22,31-55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (U.S. Patent No. 4,789,663) in view of JP 41007119A.

Wallace teaches methods of repairing bone defects or reconstructing a matrix for new bone growth, by implanting in the defect, purified, reconstituted fibrillar collagen (Type I), which may be in lyophilized form. See column 3, lines 54-64, and column 4, lines 22-32. Wallace teaches a method for preparing lyophilized collagen gel. See the example at column 10, lines 63-68, column 11, lines 1-16. Wallace also teaches a method for preparing bone collagen powder. See column 11, lines 17-68, column 12, 39.

Wallace does not particularly teach an active ingredient.

However, the Japanese reference teaches a collagen sponge containing silver sulfadiazine. See abstract.

It would have been obvious to one of ordinary skill at the time the invention was made to use the composition taught by Wallace, because Wallace teaches methods of repairing bone defects by implanting purified, reconstituted fibrillar collagen, which may be in lyophilized form. The use of an active ingredient in the composition taught by the Japanese reference would have been obvious to one of ordinary skill of the art because the Japanese reference teaches a composition which is useful for the purpose of incorporating silver sulfadiazine in a collagen sponge matrix.

The expected result would be a collagen sponge matrix which may be in lyophilized form, containing an active ingredient which is poorly soluble in water.

No claims are allowed.

Response to Arguments

1. Rejection of claims 22-30 Under 35 U.S.C. 102(b)

Applicant's arguments filed 8/5/04 have been fully considered but they are not persuasive. Applicant argues that in contrast, the Wahlig reference teaches a shaped mass resorbable in the body, which comprises collagen and a bioresorbable binding agent for collagen. The Wahlig reference teaches a collagen product that includes a polymer based binding agent for the collagen. This is in contrast to the presently claimed lyophilized collagen fibril matrix that does not require such additives.

Further, the Wahlig reference teaches away from the presently claimed lyophilized collagen fibril matrix. Wahlig teaches that release of an active ingredient

from lyophilized collagen occurs "relatively quickly", whereas the present claims are drawn to a lyophilized collagen "with a retarded release of active ingredients".

Further, all of the active agents mentioned in the Wahlig reference have good solubility in water, which is not the case with the present invention. Thus, the retarded release of the Wahlig product is related to its particular composition and structure obtained in a specific procedure involving the heating up to 200 C and pressurizing up to 1200 bar, which is in contrast to the procedure employed to prepare the active ingredient matrix according to the presently pending claims.

In response to applicant's arguments, there is no degree of release being claimed. Wahlig teaches the same ingredient as applicant, that is to say, two or more aminoglycoside antibiotics such as gentamycin and clindamycin (see col.5, lines 8-40). Wahlig teaches applicant's invention, which is resorbable collagen in lyophilized form with a delayed release of active materials (see col.3, lines 11-30 and col.2, lines 36-67). In conclusion, a product is being claimed per se, and the "containing" which is the same as "comprising" language permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive even in major amounts (*See Moleculon Research Corporation v CBS, Inc 229 USPQ 805; In re Baxter 210 USPQ 795, 803)*. Accordingly, claims 22-30 does anticipate the Wahlig ('013) reference.

2. Rejection of claims 22-28 and 30-55 under 35 U.S.C. 102(b)

In contrast, the Chu reference, while related generally to collagen implants that are useful as wound healing matrices, does not address the problems related to active

ingredients that are poorly soluble in water and body fluids. Further, collagen fibrils in suspension are used to prepare the active ingredient matrix of the presently pending claims. The inventive fibrils are obtained directly from animal skin by swelling, not dissolving. In contrast, the collagen implants of Chu are prepared from acidic aqueous solutions of collagen. In addition, the natural fibrils according to the present invention differ from the synthetic fibrils obtained after dissolving and reprecipitating collagen as taught by Chu.

In response to applicant's arguments, the Chu reference teaches the same product. Chu teaches biodegradable collagen implants, in lyophilized form containing glycosaminoglycans and bioactive agents which are added to the collagen dispersion (see col.5, lines 15-18). The theory of an active ingredient being "poorly soluble in water and body fluids" is not necessary. A product is being claimed. The "containing" language permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive even in major amounts (*See Moleculon Research Corporation v CBS, Inc 229 USPQ 805; In re Baxter 210 USPQ 795, 803)*. Accordingly, claims 22-28 and 30-55 does anticipate the Chu ('576) reference.

3. Rejection of claims 22, 31-55 under 35 U.S.C. 103(a)

The reference of record does not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. The Wallace reference fails to disclose an active ingredient. Further, the collagen fibrils of the present invention are natural lyophilized collagen fibrils. In contrast, Wallace teaches bone defect repair based on reconstituted fibrillar skin collagen or bone collagen powder. Further, the process for

preparing the lyophilized collagen fibrils of the present invention is completely different from the manner in which the reconstituted collagen of Wallace is prepared. The Japanese patent to Morita does not remedy these deficiencies. Morita teaches a sulfadiazine silver doped collagen product for use as artificial skin, prepared from a collagen solution.

In response to applicant's arguments, Wallace teaches purified collagen fibrils, which may be in lyophilized form (see col.3, lines 54-64, col.4, lines 1-55) and Morita teaches a collagen sponge containing silver sulfadiazine which is an active ingredient (see the abstract).

A product is being claimed per se and the "containing" language permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive even in major amounts (*See Moleculon Research Corporation v CBS, Inc 229 USPQ 805; In re Baxter 210 USPQ 795, 803)*. Accordingly, claims 22,31-55 are deemed obvious over the Chu ('576) reference.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard
January 26, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600